

**IN THE UNITED STATES DISTRICT COURT FOR  
THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION**

WARREN PINCHUCK and ROY SAPIR, derivatively on behalf of ABBOTT LABORATORIES,	)	
	)	
	)	
Plaintiffs,	)	
	)	
	)	NO.
MILES D. WHITE, ROBERT J. ALPERN, ROXANNE S. AUSTIN, W. JAMES FARRELL, H. LAURANCE FULLER, EDWARD M. LIDDY, PHEBE N. NOV AKOVIC, WILLIAM A. OSBORN, SAMUEL C. SCOTT III, and GLENN F. TILTON,	)	
	)	<b>JURY TRIAL DEMANDED</b>
	)	
Defendants,	)	
	)	
-and-	)	
	)	
ABBOTT LABORATORIES,	)	
	)	
Nominal Defendant.	)	

**VERIFIED SHAREHOLDER DERIVATIVE  
COMPLAINT**

Plaintiffs Warren Pinchuck and Roy Sapir (“Plaintiffs”) allege the following upon personal knowledge as to themselves, and upon information and belief as to all other allegations, based upon their attorneys’ investigation of the claims herein alleged, including, *inter alia*, United States Securities and Exchange Commission (“SEC”) filings, press releases, media stories, information from the Food and Drug Administration (“FDA”), and the Amended Complaint filed in *United States ex rel. McCoyd v. Abbott Laboratories*, No. 1:07-cv-00081-SGW (W.D. Va.) (the “qui tam Amended Complaint”):

### **SUMMARY OF THE ACTION**

1. This is a shareholder derivative action brought pursuant to Federal Rule of Civil Procedure 23.1 on behalf of nominal defendant Abbott Laboratories (“Abbott” or the “Company”), against the current members of the Company’s Board of Directors (the “Board”) for their breaches of fiduciary duties owed to Abbott arising out of the Company’s illegal off-label marketing of the drug Depakote. The Board’s breaches of their fiduciary duties have caused Abbott substantial injury.

2. Abbott is a global broad-based health care company. Among its principal operations is the development and marketing of pharmaceuticals, including Depakote. Depakote is a drug that has been approved by the FDA only for specific uses which include treatment of acute manic episodes associated with bipolar disorder, migraine headaches in adults and certain seizure disorders in adults and children ten years of age and older. It is against federal and state law to market FDA-approved drugs for uses that have not been specifically approved by the FDA (“off-label marketing”).

3. Beginning in or around 1998 and continuing for more than a decade, Abbott took substantial measures to illegally and improperly market Depakote for off-label uses, specifically targeting, among others, elderly patients suffering from Alzheimer’s disease or dementia, and children.

4. Due to the decade-long illegal and improper off-label marketing campaign, Abbott has tentatively agreed to pay at least \$1.3 billion to settle claims by the United States government and twenty-four states. The tentative agreement reached among Abbott executives, federal prosecutors and state officials will require Abbott to pay approximately \$800 million to resolve civil claims and approximately \$500 million in criminal penalties.

On October 19, 2011, Abbott announced that it had reserved \$1.5 billion “related to ongoing settlement discussions in the previously disclosed investigation by the U.S. Department of Justice, through the U. S. Attorney for the Western District of Virginia, related to Depakote.” A settlement of this amount would be the third largest illegal pharmaceutical marketing accord in U.S. history.

5. As alleged herein, the Board’s continuous and sustained actions and inactions during the decade-long period of illegal and improper off-label marketing of Depakote and their utter failure to cause Abbott and its senior executive officers to halt the illegal and improper off-label marketing of Depakote has caused significant injury and damage to Abbott, including the third largest settlement for illegal pharmaceutical marketing in United States history. The Board, including Abbott’s Chief Executive Officer (“CEO”) and Chairman, Miles D. White (“White”), caused and/or permitted Abbott to engage in a decade-long campaign to market Depakote for off-label uses, despite their knowledge that off-label marketing of an FDA-approved drug was illegal and that such action subjected Abbott to substantial monetary fines and criminal liability.

### **JURISDICTION AND VENUE**

6. This Court has jurisdiction over the subject matter of this action under and pursuant to 28 U.S.C. § 1332(a) because this action is an action for, *inter alia*, damages in excess of \$75,000, exclusive of interest and costs, and there is complete diversity of citizenship.

7. This action is not a collusive one to confer jurisdiction on a Court of the United States that it would not otherwise have.

8. Venue is proper in this District because Abbott is incorporated in this District and has its principal executive offices in this District.

### **THE PARTIES**

9. Plaintiffs each currently own shares of Abbott common stock and each has continuously owned shares in Abbott at times relevant to this action. Plaintiffs bring this action derivatively in the right and for the benefit of Abbott. Plaintiffs will fairly and adequately represent the interests of Abbott and its shareholders in enforcing the rights of the Company. Plaintiff Warren Pinchuck is a citizen of Florida and Plaintiff Roy Sapir is a citizen of New Jersey.

10. Nominal defendant Abbott is a citizen of Illinois. Abbott is an Illinois corporation with its principal place of business in Illinois.

11. Defendant White has been a director of Abbott since April 1998 and has served as Chairman of the Board since 2000. White was elected Executive Vice President on February 13, 1990, and elected CEO in January 1999. White was CEO in 1999 when Abbott entered into a consent decree with the United States Department of Justice and paid \$100 million in settlement of federal charges that Abbott had manufactured certain medical devices in violation of FDA regulations over a six-year period. Defendant White earned total compensation of \$25.6 million in 2010 despite a decrease in Abbott's net income from the prior year. In April 2011, White sold almost 200,000 shares of common stock for proceeds in excess of \$10 million.

12. Defendant Robert J. Alpern, M.D. ("Alpern") has been a director of Abbott since October 2008. Alpern has been a member of the Public Policy Committee since April 2010.

13. Defendant Roxanne S. Austin (“Austin”) has been a director of Abbott since December 2000. Austin has served on the Audit Committee since April 2001 and as its Chairman since April 2007, and has served on the Public Policy Committee since April 2003.

14. Defendant W. James Farrell (“Farrell”) has been a director of Abbott since January 2006. Farrell has been a member of the Compensation Committee and Nominations and Governance Committee since April 2006.

15. Defendant H. Laurance Fuller (“Fuller”) has been a director of Abbott since 1988. Fuller was a member of the Compensation Committee until April 1997, and has been the Chairman of the Nominations and Governance Committee since April 2003.

16. Defendant Edward M. Liddy (“Liddy”) has been a director of Abbott since June 2010 and has served on the Audit and Compensation Committees since June 2010.

17. Defendant Phebe N. Novakovic (“Novakovic”) has been a director of Abbott since June 2010. Novakovic has been a member of the Nominations and Governance Committee and Public Policy Committee since June 2010.

18. Defendant William A. Osborn (“Osborn”) has been a director of Abbott since January 2008. Osborn has served on the Compensation Committee since April 2008 and the Nominations and Governance Committee since April 2010.

19. Defendant Samuel C. Scott, III (“Scott”) has been a director of Abbott since April 2007. Scott has been a member of the Audit Committee since April 2007.

20. Defendant Glenn F. Tilton (“Tilton”) has been a director of Abbott since April 2007. Tilton has served on the Audit Committee since April 2007.

21. Defendants are citizens of states other than Florida and New Jersey.

22. Due to their positions as current or former officers and/or directors of Abbott, and because of their ability to oversee and control the business and corporate affairs of the Company, Defendants owed the Company and its shareholders the fiduciary obligations of loyalty and due care. Each defendant owed a fiduciary duty to the Company and its shareholders to exercise good faith and diligence in the administration of the affairs of the Company and in the discharge of their duties and responsibilities as directors.

23. To discharge their duties, Defendants are required to exercise reasonable and prudent oversight and supervision over the management, policies, practices, and controls of the Company. By virtue of such duties, Defendants were and are required to, among other things:

a. Manage, conduct, supervise, and direct the business affairs of Abbott in accordance with all applicable laws (including federal and state laws, government rules and regulations and the charter and bylaws of Abbott);

b. Ensure that relevant FDA regulations under which Abbott operated were followed, that violations thereof were timely corrected, and that regulatory inquiries, comments, and warnings were responded to in a timely and effective fashion;

c. Neither violate nor knowingly permit any officer, director or employee of Abbott to violate applicable laws, rules, and regulations;

d. Remain informed as to the status of Abbott's operations and upon receipt of notice or information of imprudent or unsound practices, to make a reasonable inquiry in connection therewith, and to take steps to correct such conditions or practices;

e. Conduct reasonable investigations of relevant matters;

f. Establish and maintain systematic and accurate records and reports of the business and affairs of Abbott and processes and procedures for the reporting of the business and affairs to the Board and to periodically investigate, or cause independent investigation to be made of, said reports and records; and

g. Maintain and implement an adequate, functioning system of internal controls, such that Abbott's affairs and operations would be conducted in accordance with all applicable laws, rules, and regulations.

24. Defendants, in light of their positions of control and authority as directors and/or officers of the Company, were able to and did, directly and indirectly, exercise control over the acts described herein.

25. Each defendant herein is sued individually as a conspirator, aider, and abettor, as well as in his or her capacity as a director of Abbott, and the liability of each arises from the fact that each has engaged in all or part of the unlawful acts, schemes, procedures, or transactions described of herein.

### **FACTUAL BACKGROUND**

#### **FDA Approval of Depakote**

26. A drug manufacturer must receive FDA approval for a prescription drug before the drug manufacturer markets or sells it. *See* 21 U.S.C. §§ 331, 355. Pursuant to 21 U.S.C. § 355, drug manufacturers must file an application with the FDA, which the FDA subsequently reviews to determine whether the drug's intended uses are safe and effective.

27. Under the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-397, and the Public Health Services Act ("PHS A"), 42 U.S.C. § 262 *et seq.*, drug manufacturers may not market or promote a drug for a use that the FDA has not approved. *See* 21 U.S.C. §§ 331; 42

U.S.C. §§ 262(a)(1), (b); 21 C.F.R. § 601.12. Physicians may prescribe a drug for non-FDA approved uses. However, drug manufacturers may not market or promote to physicians a drug for uses other than those approved by the FDA, as this would constitute off-label marketing or misbranding under the FDCA. 21 U.S.C. §§ 331, 352; *see also* 21 C.F.R. § 202.1.

28. According to the FDA's website, Depakote was originally approved by the FDA in March 1983. To date, the drug has been approved for: (i) treatment of the manic episodes associated with bipolar disorder; (ii) monotherapy and adjunctive therapy in the treatment of patients with complex partial seizures that occur either in isolation or in association with other types of seizures; (iii) sole and adjunctive therapy in the treatment of simple and complex absence seizures, and adjunctively in patients with multiple seizure types that include absence seizures; and (iv) prophylaxis of migraine headaches.

29. According to the FDA's website, Depakote ER was originally approved by the FDA in August 2000, and to date, has been approved for the following: (i) acute treatment of manic or mixed episodes associated with bipolar disorder, with or without psychotic features; (ii) monotherapy and adjunctive therapy of complex partial seizures and simple and complex absence seizures; (iii) adjunctive therapy in patients with multiple seizure types that include absence seizures; and (iv) prophylaxis of migraine headaches.

30. Moreover, according to the FDA's website, Depakote Sprinkle Capsules have been approved by the FDA for: (i) monotherapy and adjunctive therapy of complex partial seizures and simple and complex absence seizures; and (ii) adjunctive therapy in patients with multiple seizure types that include absence seizures.

31. Although the Depakote drugs have been approved by the FDA for the uses discussed above, the drugs have serious potential side effects. The labels that accompany

the drugs, which are available on the FDA's website, warn of, *inter alia*, hepatotoxicity (or chemical-driven liver damage, including hepatic failure resulting in fatalities), pancreatitis (including life-threatening pancreatitis), teratogenic effects and other adverse effects in pregnant women, suicidal behavior and ideation, somnolence in the elderly, thrombocytopenia, hyperammonemia, hypothermia and multi-organ hypersensitivity reactions.

32. Depakote, Depakote ER, and Depakote Sprinkle Capsules have not been approved for treatment of the following:

- Alzheimer's disease or dementia or their side effects;
- disorders or symptoms other than epileptic seizures in patients under the age of eighteen;
- disorders or symptoms in children under the age of ten;
- schizophrenia;
- attention deficit hyperactivity disorder ("ADHD");
- insomnia
- mood disorder;
- narcotic drug withdrawal;
- post-stroke seizures; or
- other forms of epilepsy.

**Off-Label Marketing of Devakote**

33. Beginning in or around 1998, Defendants caused and/or allowed Abbott to knowingly engage in repeated and persistent violations of federal law prohibiting the marketing of Depakote for uses not approved by the FDA.

34. According to the *qui tam* Amended Complaint, Abbott engaged in centrally-organized plans to illegally market Depakote. Abbott promoted Depakote for non-FDA approved uses by employing numerous tactics, including, for example, concealing what appeared to be unbiased scientific and educational programs into avenues of promoting Depakote, and providing incentives to physicians (monetary and otherwise) to encourage them to promote and prescribe Depakote for non-FDA approved uses.

35. Abbott targeted its off-label marketing towards elderly patients suffering from Alzheimer's disease or dementia. Abbott focused its efforts on, *inter alia*, nursing homes, assisted living developments, and long term care facilities, forming a sales division devoted to marketing Depakote to physicians and other health care professionals within these markets.

36. According to the *qui tam* Amended Complaint, in or around 1998, Abbott created the "Long Term Care" division, devoted exclusively to marketing Depakote to long term care facilities for non-FDA approved uses. To facilitate off-label marketing of Depakote to the geriatric markets, Abbott provided training, incentives, and compensation packages to its sales representatives, who would then market Depakote to physicians and institutions and encourage them to use Depakote in place of psychopharmacological drugs manufactured by other pharmaceutical companies.

37. Abbott hired outside consultants to train its sales representatives to off-label market Depakote to geriatric markets, which training took place off of Abbott's headquarters. The Company also selected certain Company sales representatives to teach their off-label marketing skills to other sales representatives, and held mock sales meetings and calls.

38. Abbott sales representatives were trained to use various off-label marketing techniques on physicians and other health care providers. For example, sales representatives were instructed to: use Company-approved sales aids in long term or skilled nursing facilities; provide physicians with data from expert consensus guidelines regarding dementia; and attend patient and caregiver support group meetings (including those sponsored by the Alzheimer's Association) that provided patients with information about types of treatments for dementia.

39. According to the *qui tam* Amended Complaint, Abbott also set aside significant resources for the Long Term Care division to educate physicians and other health care professionals about Depakote off-label uses. For example, Abbott representatives specially trained and provided written materials and presentations to health care professionals. Moreover, Abbott representatives, after securing advanced approval from Abbott's headquarters, provided substantial payments to physicians (through intermediaries) to promote Depakote off-label uses to other physicians at various programs and lectures, dinners, Continuing Medical Education classes ("CMEs"), and other events. Abbott also provided monetary and other incentives to physicians who prescribed large quantities of Depakote, and physicians who Abbott believed would promote or prescribe Depakote in the future. Additionally, Abbott purchased data to use to gather prescribing information about physicians practicing in long term care facilities.

40. Moreover, according to the *qui tam* Amended Complaint, Abbott's marketing department also paid for speaker events at large national meetings, such as one event in March 2003 hosted by AMDA (formerly the American Medical Directors Association), a professional association of medical directors, physicians, and others practicing in the long

term care continuum, focusing primarily on Depakote off-label uses in nursing homes. Abbott also provided funding to entities to develop therapeutic guidelines and/or disease state management programs for treating symptoms associated with dementia.

41. Abbott funded and created expert consensus pocket guidelines for use by physicians and other practitioners regarding the protocol for symptoms associated with dementia. Moreover, Abbott trained and required the Company's representatives to use the guidelines to recommend Depakote for treating symptoms associated with dementia, to educate physicians and practitioners regarding how to use Depakote to avoid Omnibus Budget Reconciliation Act requirements, and to suggest Depakote dosages for elderly patients.

42. Targeting the elderly population placed these individuals at serious risk of injury, illness, and death, and also caused them financial harm. As mentioned above, Depakote's label specifically warns of the side effect of "somnolence in the elderly." Specifically, the Depakote label states, among other things, that "[a] higher percentage of patients above 65 years of age reported accidental injury, infection, pain, somnolence, and tremor[.]" and "[a] study of elderly patients with dementia revealed drug related somnolence and discontinuation for somnolence[.]"

43. According to the *qui tam* Amended Complaint, Abbott also marketed Depakote Sprinkle Capsules for administration to elderly patients through feeding tubes. While there is no FDA-approved dosage for administration of Depakote Sprinkle Capsules through feeding tubes, Abbott representatives were directed to represent to physicians, other healthcare providers, and pharmacists that the drug may be administered this way. The

current “Administrative Guide” that accompanies the drug’s label, which is available on the FDA’s website, states:

Depakote Sprinkle Capsules (divalproex sodium coated particles in capsules) may be swallowed whole or the capsule contents may be sprinkled onto soft food such as applesauce or pudding. . . .

Place all the sprinkles onto a small amount (about a teaspoonful) of soft food such as applesauce or pudding.

Make sure that all of the sprinkle and food mixture is swallowed right away. Do not chew the sprinkle and food mixture. . . .

44. Abbott representatives were instructed to use sales aids and instruction pamphlets to teach physicians and nurses how to correctly place the contents of Depakote Sprinkle Capsules into feeding tubes and to distribute these instruction pamphlets. Abbott representatives were encouraged to promote Depakote Sprinkle Capsules mainly for geriatric patients who suffered from symptoms of dementia and who could not or refused to swallow tablets. However, as mentioned, Depakote Sprinkle Capsules are FDA approved only for monotherapy and adjunctive therapy of complex partial seizures and simple and complex absence seizures, and adjunctive therapy in patients with multiple seizure types that include absence seizures. Abbott representatives were also trained and instructed to recommend that long term health care providers place the contents of Depakote Sprinkle Capsules into patients’ foods, and focused on encouraging doctors to switch from another drug—valporate syrup, manufactured by other drug companies—to Depakote Sprinkle Capsules.

45. According to the *qui tam* Amended Complaint, Abbott representatives were also trained and directed to provide instructions for “rapid loading doses” of Depakote to treat certain instances of acute mania. Representatives used sales aids and other materials

produced by Abbott to assist in promoting to physicians the “rapid load” dosage of Depakote, although the drug does not have dosing instructions for “rapid loading.” Abbott also provided physicians with information on such dosages and paid at least one physician to produce a CME video on the topic. Representatives were also trained to encourage “rapid loading” of Depakote instead of using the drug Zyprexa (manufactured by another drug manufacturer) for individuals suffering from acute psychiatric symptoms, which is not an FDA-approved use of the drug.

46. The Company’s sales force was also trained to provide instructions for Depakote “maintenance dosing” for symptoms associated with dementia, despite the lack of FDA approval for this dosage or disease. Sales representatives were trained to suggest to physicians high doses

47. According to the *qui tam* Amended Complaint, Abbott also off-label marketed Depakote for the treatment of a number of other diseases and illnesses. For example, Abbott marketed Depakote to treat developmental delay, behavior problems, psychiatric disorders, and ADHD in children under the age of eighteen. Depakote has only been approved for treatment of *epilepsy* in children ten years of age or older, and has not been approved for treatment of developmental delay, behavior problems, psychiatric disorders, or ADHD in children. Nevertheless, in violation of applicable law, Abbott sales representatives were trained and instructed to promote Depakote for off-label use at mental health facilities that did not treat children with epilepsy, but instead treated children for developmental delay, behavior problems, psychiatric disorders, and ADHD.

48. Abbott masked off-label marketing of Depakote for unapproved uses in children by, for example, focusing on incidences of epilepsy that occur in children who

have developmental problems, and focusing on symptoms that may be present in both children with epilepsy and developmental problems. Abbott also sought physicians or experts to promote Depakote for developmental delay.

49. According to the *qui tam* Amended Complaint, Abbott off-label marketed Depakote for the treatment of depression associated with bipolar disorder in children and adults. As discussed above, Depakote has been approved by the FDA for treatment of only *manic* episodes associated with bipolar disorder, and Depakote ER has been approved for acute treatment of manic or mixed episodes associated with bipolar disorder. However, neither has been approved for the treatment of bipolar depression or for treatment of bipolar disorder in children.

50. Abbott representatives promoted Depakote for these off-label uses and encouraged its use over drugs manufactured by other companies, such as Lamictal, which is used for the long-term treatment of bipolar I disorder. Abbott paid physicians to provide lectures to other physicians about bipolar depression and/or prescribing Depakote for treatment of bipolar depression. Abbott representatives were trained to market the drug for treatment of bipolar depression. They were taught to focus on the negative side effects of drugs such as Lamictal, and were taught how to respond to objections from psychiatrists regarding prescribing Depakote for treating children with bipolar disorder. Abbott representatives were also instructed to use only certain information from studies to discredit trials referenced in Lamictal's sales aids, and to provide materials produced by Abbott that discussed Depakote off-label uses in children.

51. According to the *qui tam* Amended Complaint, Abbott also marketed Depakote for the treatment of schizophrenia and other psychological disorders, which are

not FDA approved uses of the drug. Company sales representatives were directed to use Abbott sales aids and studies to market Depakote for the treatment of psychosis or schizophrenia.

52. Moreover, according to the *qui tam* Amended Complaint, Abbott off-label marketed Depakote for treatment of, *inter alia*, post-seizure stroke, epilepsy in children under the age of ten, and addictive narcotic drug withdrawal. For example, Abbott funded events where Abbott-paid physicians promoted the use of Depakote to treat symptoms of narcotic drug withdrawal, and created materials on this non-FDA approved use that were distributed to, among others, physicians paid to lecture on the off-label uses. Abbott also misrepresented that Depakote lowered cholesterol. Abbott sales representatives were instructed to inform physicians that the drug had a “metabolically neutral” side effect, when in fact Abbott’s data indicated that Depakote lowered not only LDL cholesterol (the “bad” cholesterol), but also HDL cholesterol (the “good” cholesterol). Representatives used Abbott sponsored CME and study materials and sales aids to misrepresent this effect of Depakote.

53. Beginning in 2007, several *qui tam* actions were filed against Abbott in connection with the Company’s off-label marketing of Depakote, which were ultimately consolidated in the United States District Court for the Western District of Virginia.

54. Meredith McCoy, who was employed by Abbott as a pharmaceutical sales representative from February 1998 until June 2007 and who specifically promoted Depakote during that period, filed a complaint against Abbott on October 31, 2007, and subsequently filed the *qui tam* Amended Complaint on behalf of the United States of America, twenty-four states, the District of Columbia, and Chicago. In the *qui tam* Amended Complaint, Plaintiffs alleged that Abbott (and several other defendants, whose names have not been

publicly released) violated the False Claims Act, 31 U.S.C. § 3729 *et seq.*, and similar state and municipal laws in connection with, among other things, off-label marketing of Depakote. Specifically, the *qui tam* Amended Complaint alleged:

[Abbott] knowingly presented or caused to be presented false or fraudulent claims to be submitted in violation of the law for payment or approval by federal and state agencies and/or programs by:

- systematically engaging in illegal off-label marketing of Abbott's anti-epileptic drug, Depakote (generic name divalproex sodium);
- furthering the unlawful off-label marketing of Depakote through the transformation of ostensibly independent and unbiased educational and scientific programs, including physician continuing medical education ("CME") programs, into promotional vehicles for Depakote; and
- unlawfully promoting Depakote in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), as amended by the Patient Protection and Affordable Care Act ("PPACA"), Public Law No. 111-148, Sec. 6402(g), and the Stark Law, 42 U.S.C. § 1395nn, and 42 C.F.R. § 411.350 *et seq.* by providing cash and other incentives to induce doctors to promote and prescribe Depakote, including for off-label uses.

55. The *qui tam* Amended Complaint further alleged:

A substantial portion of Depakote prescriptions are paid for by Medicare, Medicaid and other government-funded health insurance programs. Prescriptions for uses other than those that are approved by the FDA or included in certain government-approved compendia are not reimbursable.

The complaint alleged that these programs were harmed because, among other things, they paid for off-label prescriptions, were required to pay for treating negative side effects in patients who were prescribed Depakote, and health care providers submitted false claims to be paid by the programs.

56. The United States Department of Justice began a civil and criminal investigation of Abbott's off-label marketing of Depakote.

57. On at least one occasion, on January 22, 2009, the Division of Drug

Marketing, Advertising, and Communications (“DDMAC”) of the FDA sent a letter (the “Warning Letter”) to Rick Leber, Regulatory Manager at Abbott, in connection with a specific marketing material, referred to therein as a Depakote ER/Depakote Continuum Care Pharmacy Formulary Flashcard for Depakote (the “Flashcard”). The Warning Letter stated, among other things, that “[t]he Flashcard is misleading because it ... broadens the indication of Depakote ER[.] . . . Thus, *this promotional material misbrands the drugs in violation of the Federal Food, Drug, and Cosmetic Act* (the Act), 21 U.S.C. 352(a) and 321(n).” (Emphasis added). The Warning Letter further stated that “[t]he Flashcard is misleading because it *implies that Depakote ER is indicated for use in a broader range of mania patients than Depakote, when this is not the case.*” (Emphasis added). The Warning Letter continued: “Additionally, we note that the Flashcard fails to include specific indications for Depakote.” In the Warning Letter, “DDMAC request[ed] that Abbott immediately cease the dissemination of violative promotional materials for Depakote and Depakote ER such as those described above.”

58. According to the *qui tam* Amended Complaint, the illegal and wrongful actions alleged above were orchestrated and condoned by the highest levels of Abbott’s management.

The Long Term Care division was created and/or maintained with the knowledge and consent of Abbott management, including an undisclosed member of management.<sup>1</sup> Abbott upper level management attended Depakote sales training sessions but purposefully left the room when the off-label training sessions began, and while a sales representative was told

---

<sup>1</sup> The *qui tam* Amended Complaint was filed under seal pursuant to 31 U.S.C. § 3730(b)(2), and certain individuals’ names have been redacted from the public version, including this member of management.

by her managers that Abbott upper level management knew about off-label training sessions, they did not want to personally witness them. Management staff at Abbott's corporate headquarters were fully aware of Depakote's speaker programs and events that the Company underwrote financially. Abbott required Long Term Care/Special Accounts division representatives to secure advanced approval from Abbott headquarters for payments for the events and payments to physicians.

59. On March 15, 2010, Abbott filed a Form DEF 14A with the SEC which disclosed: "In accordance with Abbott's articles of incorporation, Abbott has advanced defense costs on behalf of three former officers in connection with the United States Department of Justice's criminal and civil investigation of Abbott's Depakote sales and marketing activities."

60. Abbott made similar statements in its Form DEF 14A filed by Abbott with the SEC on March 15, 2011:

In accordance with Abbott's articles of incorporation, Abbott has advanced defense costs on behalf of two current and five former officers in connection with the United States Department of Justice's criminal and civil investigation of Abbott's Depakote sales and marketing activities. Abbott has advanced defense costs on behalf of a current officer in connection with AMO [Advanced Medical Optics, Inc., a subsidiary of Abbott].

61. On October 19, 2011, Abbott filed a Form 8-K with the SEC attaching its press release announcing Abbott's financial results for the third quarter ended September 30, 2011. The press release included the statement that the Company had reserved \$1.5 billion "related to ongoing settlement discussions in the previously disclosed investigation by the U.S. Department of Justice, through the U. S. Attorney for the Western District of Virginia, related to Depakote."

#### **DEFENDANTS' WRONGDOING**

62. According to the Company's most recent Definitive Proxy Statement filed on Form DEF 14A with the SEC on March 15, 2011:

The board has risk oversight responsibility for Abbott and administers this responsibility both directly and with assistance from its committees. The board has determined that the current leadership structure, in which the offices of chairman and chief executive officer are held by one individual and an independent director acts as lead director, ensures the appropriate level of oversight, independence, and responsibility is applied to all board decisions, including risk oversight, and is in the best interests of Abbott and its shareholders. The chairman of the nominations and governance committee acts as the lead director to facilitate communication with the board and presides over regularly conducted executive sessions of the independent directors or sessions where the chairman of the board is not present. It is the role of the lead director to review and approve matters, such as agenda items, schedule sufficiency, and, where appropriate, information provided to other board members. The lead director is chosen by and from the independent members of the board of directors, and serves as the liaison between the chairman and the independent directors; however, all directors are encouraged to, and in fact do, consult with the chairman on each of the above topics as well. The lead director, and each of the other directors, communicates regularly with the chairman and chief executive officer regarding appropriate agenda topics and other board related matters.

The Company's previous proxy statements have similar explanations of the Board's oversight responsibility.

63. According to Abbott's proxy statements, the Board met officially eight times in 1998, ten times in 1999, six times in 2000, six times in 2001, eight times in 2002, eleven times in 2003, eight times in 2004, eight times in 2005, thirteen times in 2006, seven times in 2007, nine times in 2008, seven times in 2009, and seven times in 2010.

64. As a matter of corporate governance in connection with Board meetings, senior officers of Abbott and/or members of the Company's committees prepared packages of relevant information concerning the business and financial position of the Company, including internal audit reports that detailed the functions of critical departments of the Company, litigation reports detailing pending or possible litigation or regulatory

actions concerning the Company. Defendants, under existing principles of corporate law and governance, had the responsibility to ensure that Abbott had in place a reporting system that would enable them to determine if Abbott's activities complied with applicable law and whether proper reports were being generated.

65. Abbott currently has, and for substantially the duration of the relevant period had, five committees: the Public Policy Committee, Audit Committee, Executive Committee, Compensation Committee, and Nominations and Board Affairs Committee.

66. According to the Company's Public Policy Committee charter:

*Purpose.* The Public Policy Committee of the Board of Directors shall assist the Board in fulfilling its oversight responsibility with respect to: public policy, regulatory (including regulation by the Federal Food and Drug Administration, as well as other domestic, foreign and international regulatory bodies) and government affairs and health care compliance issues that affect Abbott (recognizing that other board committees assist the Board of Directors in reviewing certain areas of legal and regulatory compliance), by discharging the responsibilities set forth below ....

*Authority and Responsibilities.* To assist it in the conduct of its responsibilities, the Public Policy Committee shall consult with management and, to the extent it deems it necessary or appropriate, may seek advice and assistance from Abbott employees or others, and may retain legal counsel and other advisors.

The Public Policy Committee shall report to the Board on a regular basis.

The Public Policy Committee may delegate any of its responsibilities and duties to one or more members of the Public Policy Committee.

The Committee shall:

- Review and evaluate Abbott's policies and practices with respect to maintaining legal, regulatory and health care compliance (recognizing that other board committees assist the Board of Directors in reviewing certain areas of legal and regulatory compliance), and review them with the Board as appropriate.
- Devise a process for the dissemination of information to the Committee from management with respect to regulatory and healthcare

compliance matters, including, as appropriate, presentations to the Committee from management concerning the state of regulatory compliance and all issues with respect thereto.

- The Chief Ethics and Compliance Officer shall report to the Public Policy Committee on an as needed basis on any significant compliance issues.
- Review and evaluate Abbott's policies and practices with respect to social responsibility, and review them with the Board as appropriate.
- Review social, political, economic and environmental trends and public policy issues that affect or could affect Abbott's business activities, performance, and public image, and review them with the Board as appropriate.
- Review and make recommendations to the Board regarding shareholder proposals submitted for inclusion in Abbott's proxy materials that relate to public policy or social responsibility issues.

67. According to the Company's proxy statements, the Public Policy Committee- which was created in October 1999, includes certain of the Director Defendants, and was charged with assisting the Board in fulfilling its oversight responsibility with respect to, among other things, legal, regulatory, and healthcare compliance (including regulation by the FDA)- officially met three times in 2000, three times in 2001, three times in 2002, two times in 2003, two times in 2004, two times in 2005, one time in 2006, two times in 2007, once in 2008, two times in 2009, and once in 2010.

68. Moreover, according to Abbott's Audit Committee charter:

*Purpose.* The Audit Committee of the Board of Directors shall assist the Board in fulfilling its oversight responsibility with respect to:

- Abbott's accounting and financial reporting practices and the audit process;
- the quality and integrity of Abbott's financial statements;
- the independent auditors' qualifications, independence, and performance;

- the performance of Abbott's internal audit function and internal auditors;
- legal and regulatory compliance as it relates to financial matters, including accounting, auditing, financial reporting, and securities law issues (recognizing that other board committees assist the Board of Directors in reviewing other areas of legal and regulatory compliance); and
- Abbott's enterprise risk management, including major financial risk exposures (recognizing that other board committees assist the Board of Directors in reviewing certain aspects of risk management);

and shall prepare the report required by the rules of the Securities and Exchange Commission to be included in Abbott's annual proxy statement. ...

Among other things, the Audit Committee was required to:

Review and discuss (with management, the internal auditors and the independent auditors, as appropriate) Abbott's enterprise risk management, including major financial risk exposures, and the steps management has taken to monitor and control those exposures, including Abbott's risk assessment and risk management policies.

69. The Audit Committee, which includes certain of the Defendants and assists the Board in fulfilling its oversight responsibilities and with certain areas of legal and regulatory compliance, met officially two times in 1998, two times in 1999, three times in 2000, four times in 2001, seven times in 2002, seven times in 2003, seven times in 2005, seven times in 2006, six times in 2007, seven times in 2008, seven times in 2009, and seven times in 2010.

70. Moreover, Abbott's Executive Committee, which may exercise all the authority of the Board in the management of Abbott, except for matters expressly reserved by law for Board action, met once in 2003, three times in 2006, once in 2008, and three times in 2010.

71. The Company's Compensation Committee, which assists the Board in

carrying out its responsibilities relating to the compensation of Abbott's executive officers and directors, met officially three times in 1998, two times in 1999, two times in 2000, two times in 2001, three times in 2002, four times in 2003, eight times in 2004, two times in 2005, three times in 2006, three times in 2007, four times in 2008, three times in 2009, and five times in 2010.

72. The Nominations and Board Affairs Committee-which assists the Board in identifying individuals qualified to become Board members and recommends to the Board the nominees for election as directors at the next annual meeting of shareholders, recommends to the Board the persons to be elected as executive officers of Abbott, develops and recommends to the Board the corporate governance guidelines applicable to Abbott, and serves in an advisory capacity to the Board and the Chairman of the Board on matters of organization, management succession plans, major changes in the organizational structure of Abbott, and the conduct of Board activities-officially met three times in 1998, two times in 1999, two times in 2000, two times in 2001, three times in 2002, two times in 2003, two times in 2004, four times in 2005, six times in 2006, two times in 2007, three times in 2008, two times in 2009, and twice in 2010.

73. Defendants (for the years in which they were directors) signed Abbott's Forms 10-K filed with the SEC each year during the relevant period and, in so doing, were required to assure themselves, through their due diligence of the matters discussed therein and of Abbott's business, operations, and finances, that the Forms IO-K filed with the SEC were accurate. Through this process the Director Defendants were required to make themselves aware of Abbott's regulatory status and exposure, including the continuing practices of off-label marketing of Depakote. For example, the Company's most recent

Form 10-K, filed on February 18, 2011, discusses the following items, each of which the Director Defendants who were directors at that time, by signing the Form IO-K, presumably investigated to assure themselves that the descriptions were accurate:

Regulation: The development, manufacture, sale, and distribution of Abbott's products are subject to comprehensive government regulation. Government regulation by various federal, state, and local agencies, both domestic and international, which includes detailed inspection of, and controls over, research and laboratory procedures, clinical investigations, product approvals and manufacturing, marketing and promotion, sampling, distribution, record keeping, storage, and disposal practices, and achieving compliance with these regulations, substantially increases the time, difficulty, and costs incurred in obtaining and maintaining the approval to market newly developed and existing products. Government regulatory actions can result in delay in the release of products, seizure or recall of products, suspension or revocation of the authority necessary for their production and sale, and other civil or criminal sanctions, including fines and penalties....

Abbott's products are subject to rigorous regulation by the U.S. Food and Drug Administration, and numerous international, supranational, federal, and state authorities....

Abbott's industry is also subject to various federal, state, and international laws and regulations pertaining to government benefit program reimbursement, price reporting and regulation, and health care fraud and abuse, including anti-kickback and false claims laws, the Medicaid Rebate Statute, the Veterans Health Care Act, and individual state laws relating to pricing and sales and marketing practices. Violations of these laws may be punishable by criminal and/or civil sanctions, including, in some instances, substantial fines, imprisonment, and exclusion from participation in federal and state health care programs, including Medicare, Medicaid, and Veterans Administration health programs. These laws and regulations are broad in scope and they are subject to evolving interpretations, which could require Abbott to incur substantial costs associated with compliance or to alter one or more of its sales or marketing practices. In addition, violations of these laws, or allegations of such violations, could disrupt Abbott's business and result in a material adverse effect on Abbott's revenues, profitability, and financial condition.

This Form 10-K was signed defendants.

74. Additional Forms 10-K filed during the relevant period contain paragraphs

similar to those above, and were signed by the Defendants who served at the time.

**DERIVATIVE ALLEGATIONS**

75. Plaintiffs incorporate by reference all preceding and subsequent paragraphs as if set forth fully herein.

76. Plaintiffs bring this action derivatively in the right and for the benefit of the Company to redress injuries suffered and to be suffered by the Company because of the breaches of fiduciary duties by Defendants.

77. Plaintiffs will adequately and fairly represent the interests of the Company and its shareholders in enforcing and prosecuting its rights, and has retained counsel experienced in litigating actions of this type.

**DEMAND IS EXCUSED**

78. Plaintiffs incorporate by reference all preceding and subsequent paragraphs as if set forth fully herein.

79. Abbott is incorporated in Illinois, and, thus, Illinois corporation law governs the issue of whether Plaintiffs were required to make a demand on the Company's Board to institute this case before filing this Complaint. Making a demand is considered futile under Illinois law if particularized facts raise a reasonable doubt that either (1) the directors are disinterested or independent, or (2) the challenged transaction was the product of a valid exercise of the directors' business judgment.

80. Plaintiffs have not made any demand on the Abbott Board to institute an action against itself for their breaches of fiduciary duties as alleged herein because such demand would be a futile and useless act, under Illinois law and its application in *In re Abbott Laboratories Derivative Shareholder Litigation*, 325 F3d 795 (7<sup>th</sup> Cir. 2003) for the

following reasons:

a. The facts detailed above demonstrate and are the basis for the allegations that Defendants: caused and/or allowed or permitted Abbott to knowingly engage in repeated and persistent violations of federal regulations in connection with the off-label marketing of Depakote; knew that the failure to comply with regulations would result in severe penalties; and chose not to bring a prompt halt to the improper conduct causing the non-compliance, reprimand those persons involved, or seek to redress Abbott for the serious damages it has and will sustain;

b. The magnitude and duration of the wrongdoing, as alleged herein, and the magnitude of the proposed \$1.3 billion settlement, reflect a lack of good faith on the part of the Director Defendants; and

c. The Board, by its actions and inactions, knowingly breached its fiduciary duties to Abbott and its shareholders.

81. Demand is also excused as futile because the facts pled herein raise a reasonable doubt that a majority of the Board is independent and disinterested. Upon information and belief, a majority of the Board members who would have reviewed the demand were directors who had been Board members during a portion and/or all of the period in question, and, thus, face a substantial likelihood of liability for deliberately and consciously failing to comply with their fiduciary duties.

## **COUNT I**

### **BREACH OF FIDUCIARY DUTIES**

82. Plaintiffs incorporate by reference all preceding and subsequent paragraphs as if set forth fully herein.

83. Each Defendant, because of his/her position as a director and, with respect to White, CEO, owed fiduciary duties to the Company and its shareholders in connection with the management and operations of the Company's business and operations.

84. To properly discharge these duties, Defendants were required to, among other things:

a. manage, conduct, supervise, and direct the business affairs of Abbott in accordance with best practices, and applicable state and federal laws, rules, and regulations;

b. neither violate nor permit any officer, director, agent, or employee of Abbott to violate applicable state and federal laws, rules, or regulations; and

c. remain informed as to the status of Abbott's business practices and operations and upon receipt of notice of information of imprudent or unsound practices or operations, make a reasonable inquiry in connection therewith, and take steps to correct such practices or operations.

85. Moreover, each Defendant had a duty to Abbott and its shareholders to establish and maintain adequate internal controls to ensure that the Company was operated in a prudent and lawful manner. Defendants had an affirmative obligation to install an internal control system to discover wrongdoing. Additionally, where red flags exist, Defendants have an obligation to take affirmative steps to address such issues.

86. As detailed herein, Defendants caused and/or allowed the Company to violate federal regulations and/or failed to properly and adequately maintain a system of internal controls adequate to insure the Company's compliance with, among other things, federal regulations, in violation of their fiduciary duties. Defendants permitted the existence of a

corporate culture that encouraged and rewarded financially unlawful and irresponsible activity resulting in the likely loss of \$1.3 billion or more.

87. As a result of Defendants' wrongful conduct and actions, Abbott has suffered and will continue to suffer significant damage.

88. All of the Defendants, individually and in concert, engaged in the aforementioned conduct in intentional breach and/or reckless disregard of their fiduciary duties to the Company and conspired to, and did, abuse the control vested in them by virtue of their high-level positions in the Company.

89. As a direct and proximate result of the Defendants' violations of their fiduciary obligations, Abbott engaged in unlawful activities causing damage to the Company.

#### **PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiffs pray for relief and judgment as follows:

A. Authorizing the maintenance of this action as a derivative action, with Plaintiffs as derivative Plaintiffs;

B. Declaring that Defendants have violated their fiduciary duties to the Company;

C. Awarding against each and all of the Defendants and in favor of the Company the amount of damages sustained by the Company as a result of Defendants' breaches of fiduciary duties;

D. Awarding to Plaintiffs their costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and

E. Granting such other and further relief as the Court deems just and proper.

**JURY DEMAND**

Pursuant to Fed. R. Civ. P. 38(b), Plaintiffs demand trial by jury on all claims asserted herein.

Dated: November 29, 2011

Plaintiffs,

By: /s/Marvin A. Miller

MARVIN A. MILLER

**MILLER LAW LLC**

115 South LaSalle Street, Suite 2910

Chicago, IL 60603

Telephone: 312-332-3400

Fax: 312-676-2672

DEBORAH R. GROSS

ROBERT P. FRUTKIN

**LAW OFFICES**

**BERNARD M. GROSS, P.C.**

100 Penn Square East

Suite 450, Wanamaker Bldg.

Philadelphia, PA 19107

Telephone: 215-561-3600

Fax: 215-561-3000

*Attorney for Plaintiffs*

PAGE 01/01

# VERIFICATION OF WARREN PINCHUCK

STATE OF FLORIDA )  
 ) ss:  
COUNTY OF PALM BEACH )

I, Warren Pinchuck, hereby verify that:

1. I have reviewed the Verified Shareholder Derivative Complaint ("Complaint") prepared on behalf of nominal defendant Abbott Laboratories ("Abbott"), and I authorize its filing.

2. I have reviewed the allegations made in the Complaint, and to those allegations of which I have personal knowledge, I believe those allegations to be true. As to those allegations of which I do not have personal knowledge, I rely on my counsel and their investigation and for that reason believe them to be true.

3. I further declare that I am a current holder of Abbott common stock and have held the stock continuously during periods relevant to the allegations in the Complaint.

Warren Pinchuck

**VERIFICATION OF**

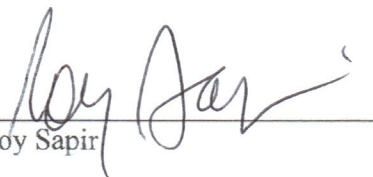
STATE OF NEW JERSEY            )  
  ) ss:  
COUNTY OF MERCER            )

I, Roy Sapir, hereby verify that:

1.       I have reviewed the Verified Shareholder Derivative Complaint  
("Complaint") prepared on behalf of nominal defendant Abbott Laboratories ("Abbott"),  
and I authorize its filing.

2.       I have reviewed the allegations made in the Complaint, and to those  
allegations of which I have personal knowledge, I believe those allegations to be true. As  
to those allegations of which I do not have personal knowledge, I rely on my counsel and  
their investigation and for that reason believe them to be true.

3.       I further declare that I am a current holder of Abbott common stock and  
have held the stock continuously during periods relevant to the allegations in the  
Complaint.

  
\_\_\_\_\_  
Roy Sapir